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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kelly R. Brown

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MCCARTER & ENGLISH, LLP
FOUR GATEWAY CENTER
100 MULBERRY STREET
NEWARK, NJ 07102

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/892,993	Applicant(s) BROWN ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, declaration, amendment and remarks filed 6/18/08. New claim 45 is added. Claims 26-44 are amended. Claims 26-45 are pending.

Previous rejections and objections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 26-28, 33-44 remain rejected and new claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec.

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2000, cited in applicant's specification at paragraph [0008] of the published application) for reasons of record and reiterated herein below with modification to address the amendment.

Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3rd and 4th full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claims and also meets claim 33 and also of claims 34-44 with the pores within the phases meeting the plurality of pores claimed in claims 39-41; since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that claims 42-44 are met; boring a receptacle space at the gradient junction of the site of injury as recited in claim 26-28 read on the experimental design of Niederauer where defect sites are made in the right and left stifles and bilateral arthrotomies performed to place the implants (paragraph 2.4 at page 2564); the scaffold is implanted into the prepared knees. Niederauer is silent on placing the ceramic phase next to the bony tissue and placing the polymer phase next to the cartilage tissue. The interphase region exhibiting gradual transition between the ceramic and polymer layers recited in new claim 45 is what the layer is capable of doing/undergoing. However, it is known in the art that ceramics closely resemble constituents of natural bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Niederauer to repair articular cartilage by placing the ceramic phase of the scaffold next to the bony tissue since the ceramic material closely resembles the bony tissue so that the bony tissue would grow into the ceramic tissue during the repair process.

4. Claims 26-44 remain rejected and new claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000, cited in applicant's specification at paragraph [0008] of the published application) in view of Vyakarnam et al. (US 6,306,424) for reasons of record and reiterated herein below with modification to address the amendment.

5. Niederauer is discussed above for rendering prima facie obvious claims 26-28 and 33-45. While Niederauer describes a scaffold that is made up of porous polymer phase and porous ceramic phase, Niederauer does not describe any of the porous phases as foamed material as claimed in claims 29-32. However it is known to use porous and foamed scaffold for repair or regeneration of tissues as taught in Vyakarnam (column 1, lines 17-21 and Title) and the porous structures are formed by lyophilization (column 4, lines 11-24). The foamed scaffold meets the limitation of claim 29; lyophilization to make foamed structure meets claims 30-32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form porous foamed scaffold structure by lyophilization with the expectation of obtaining organization at the microstructural level that facilitates tissue repair/regeneration.

Response to Arguments

6. Applicant's arguments filed 6/18/08 have been fully considered but they are not persuasive.

7. Applicant argues Niederauer does not anticipate or render obvious the present invention in amended claim 26; a) that the scaffold in Niederauer is significantly different from the novel scaffold of claim 26 because the ceramic and polymer phases of Niederauer are blended together

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and the phases glued together while the scaffold of claim 26 has discrete porous ceramic and porous polymer layers with the layers separated by an interphase, and having a portion of the polymer layer partially infused into a portion of the ceramic layer at the interphase resulting in gradual transition between the ceramic and polymer layers and mechanical interlocking between the ceramic and polymer layers; b) that in claim 26, the ceramic layer is placed adjacent to the bony tissue and the polymer layer is placed next to the cartilaginous tissue and because the scaffold of Niederauer is a composite, both the ceramic and polymer phases would be undesirably positioned adjacent to bony tissue and to cartilaginous tissue; c) the Vyakarnam reference does not disclose or suggest any interaction between a polymer phase and a ceramic phase and an interphase region where a portion of the polymer layer is at least partially infused into a portion of the ceramic so that the polymer and ceramic phases are mechanically interlocked; d) the Vyakarnam reference alone or in combination with Niederauer does not anticipate or render obvious the claim 26 and claim 26 is in condition for allowance. Therefore, applicant says that claims 29, 30, 33, 34, 39, 42 and new claim 45 that depend directly or indirectly on claim 26 are thus allowable; e) that new claim 45 requires the interphase region to exhibit gradual transition between the ceramic and polymer layers; f) that amended claims 27 and 28 are allowable because they are similar in scope to claim 26 and patentable over Niederauer in view of Vyakarnam so that claims 31, 35, 36, 40 and 43 that depend directly or indirectly from amended claims 27 and claims 32, 37, 38, 41 and 44 that depend directly or indirectly from claim 28 are allowable and patentable over the art; g) the exhibit of the declaration of Mr. Yufu Li shows the sectional views of the instant scaffold and the scaffold of the prior art with the declaration pointing to the differences between the scaffold of the invention and that of the art.

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8. **Response:** The examiner disagrees.

9. Niederauer renders obvious claims 26-28 and 33-45 as described in the rejections and Niederauer in view of Vyakarnam renders obvious claims 29-32 as described in the rejections above. Regarding a), it is noted that the Niederauer ceramic and the polymer phases are both each porous and the discrete ceramic and polymer layers of the claims read of the discrete polymer and ceramic phases of the prior art; there is an inherent interphase when the phases are glued together; since the phases are glued together, it flows that the polymer phase and the ceramic phase interacts at the interphase of junction where they are glued; applicant's admission of the gluing together of the polymer and ceramic phases of the prior art is further representation for discrete phases with the region at which the two phases are glued together representing the interphase region such that the polymer and the ceramic phases being porous interact through the interphase region; regarding b) it is noted that because the ceramic closely resembles the constituents of natural bone, the skilled artisan would naturally place the ceramic phase next to the bony tissue to achieve the expected result of articular cartilage repair during which the bony tissue would grow into the ceramic phase. Once the ceramic phase is placed next to the bony tissue, it would only flow that the polymer phase would be placed next to the cartilaginous tissue; regarding c) it is noted that Vyakarnam was not relied upon for teaching discrete polymer and ceramic phases, but was relied upon for teaching porous and foamed scaffold for repair and regeneration of tissues with the foamed scaffold meeting the limitations of claims 30-32; therefore, for d) the combination of Niederauer and Vyakarnam renders obvious the claimed invention in which foamed and porous scaffold is used. By the same argument and the rejections above, the claims dependent on claim 26 are rendered obvious by Niederauer, and Niederauer in combination with Vyakarnam. Regarding e) gradual transition between the

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ceramic layer and the polymer layer is inherent to the junction between the ceramic and polymer phases through which the polymer and the ceramic phases interact; regarding f), amended claims 27 and 28 are not allowable just as claim 26 is not allowable; regarding g) the declaration by Mr. Yufu Li will be addressed under a different section below.

10. Furthermore, in Niederauer, the cartilage phase is composed of polymer and reinforced polyglycolic (polymer) fibers, the bone phase comprises polymer and bio-glass, (see table 1, implants C and D); Niederauer specifically discloses that the implant construct is a three layer construct comprising a thin dense film on the articulating surface, porous cartilage phase and fully dense bone phase (paragraph 2.2) and the implant is assembled by cutting the porous stock materials and using small amount of solvent to glue together the various phases

11. **Declaration of Mr. Yufu Li under 37 CFR 1.132**

The declaration under 37 CFR 1.132 filed 6/18/08 is insufficient to overcome the rejection of claims 26-45 based upon Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000) and Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000), in view of Vyakarnam et al. (US 6,306,424) applied under 35 USC 103 as set forth in the last Office action dated 2/17/08 and reiterated herein because: the declaration is an opinion declaration using diagrammatical representation to show the difference between the claimed scaffold and the scaffold of the prior art. Specifically, the diagram of the cross sectional view of the inventive structure in the center is similar to the diagram of the prior art structure. Further also, the diagram provided for Niederauer appears to represent the cross section of the bone

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phase, which is comprised of the bio-glass or ceramic and the polymer (see Table 1 and 3rd and 4th full paragraphs of page 2563 and ignores the implant assembly or the scaffold assembled by gluing of the phases, the cartilage phase which is all polymer and the bone phase which is ceramic in carrier polymer. The declaration does not provide factual differences between the claimed scaffold and the scaffold of the prior art.

No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618